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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/602,597 06/22/00 DUHL

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CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
P.O. BOX 8097
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EXAMINER

WEGERT, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

11/02/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/602,597

Applicant(s)

DUHL ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 17-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 and 11-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The Amendment and Information Disclosure Statement, filed 14 August 2001 (Paper Nos. 14 and 15, respectively) have been entered. Claim 10 was cancelled. Claims 1-9 and 17-25 are drawn to non-elected inventions. Claims 11-16 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the disclosure for informalities as set forth at pp. 2-3 of the previous Office Action (Paper No. 13, 17 May 2001) is *withdrawn* in view of the amendment correcting same (Paper No. 14, 14 August 2001).

The objection to the Title as set forth at p. 2 of the previous Office Action (Paper No. 13, 17 May 2001) is *withdrawn* in view of the amendment correcting same (Paper No. 14, 14 August 2001).

The objection to the specification for citing serial numbers of patent applications that must be updated as to status changes (Paper No. 13, 17 May 2001) is *withdrawn* in view of the explanation by Applicant (Paper No. 14, 14 August 2001). Applicant is requested to update the status of these applications as their status changes.

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The objection to the claims for reciting non-elected inventions (Paper No. 13, 17 May 2001, page 4) is withdrawn in view of the amendment correcting the claims (Paper No. 14, 14 August 2001).

The objection to the Information Disclosure Statement filed in Paper No. 6 (11/20/00) for: a reference that failed to be in English, and for the Applicant failing to explain the significance of the untranslated reference or to point out relevant regions of the cited DNA sequence is *withdrawn* in view of the newly-submitted translation of the reference.

The rejection of claim 10 for lack of written description under 35 U.S.C. 112 (Paper No. 13, 17 May 2001, page 9) is *withdrawn* in view of the amendment canceling the claim (Paper No. 14, 14 August 2001).

Maintained Objections And/Or Rejections

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). This includes Provisional Application 60/141,753.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 35 USC § 112--first paragraph, utility/enablement

Claims 11-16 are rejected under 35 U.S.C. 101 and 112, first paragraph, as lacking utility and not being enabled for lack of utility. The reasons for this rejection are set forth at pp. 4-8 of the previous Office Action (Paper No. 13, 17 May 2001).

Applicants argue (pp. 3-5, Paper No. 14, 14 August 2001) that the specification discloses a polypeptide with 67-89% homology to rat plasmolipin, and that this level of homology imparts function upon the claimed polypeptide. Applicants begin their arguments by pointing to U.S. Patent 5,843,714 (Au-Young, et al, July, 1996) in which the disclosed human proteolipid has 43% homology to rat plasmolipin GI 1346732. The applicants note that the polypeptide of the Instant Application bears higher homology to the same rat plasmolipin and that this high homology would impart utility to the claimed polypeptide. The applicants also discuss a journal article by Gillen, et al (1999) in which those researchers found that rat sciatic nerve axons, regenerating after injury, display increased transcript levels of plasmolipin.

Applicant's arguments (pp. 3-5, Paper No. 14, 14 August 2001) have been fully considered but are not deemed to be persuasive for the following reasons:

To address the comparison of the Instant Application to prior Patent 5,843,714 (Au-Young, et al, July, 1996): The current rejection is in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial utility. Additionally, each Patent Application is examined on its own merits. What was deemed allowable in one Patent has no bearing on this Application.

Homology to rat plasmolipin is the crux of the applicants' arguments that the polypeptide of the Instant Application has patentable utility. However, homology is insufficient unless accompanied by assays of a protein's function. This is evident by examples of numerous polypeptides bearing high homology, yet disparate functions. For example, PTH and PTHrP are two structurally closely related proteins, which can have opposite effects on bone resorption

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(Pilbeam et al., 1993, Bone 14:717-720; see p. 717, second paragraph of Introduction).

Likewise, Kopchick et al. (U.S. Patent 5,350,836) disclose several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (column 2, lines 37-48). These examples and others illustrate that it is not predictable as to which amino acids are necessary to maintain the functional characteristics of a protein, and that even very high homology is not necessarily predictive of function. Examples from the receptor art demonstrate polypeptides with high homology having a wide-variety of functions in organisms (Ji, et al, 1998, JBC, 273:17299). Even closely-related family members sometimes work very differently and have different specific functions in the organism (Ji, et al, 1998, p. 17302, 3rd paragraph). Therefore, one skilled in the art would not know the utility and function of the claimed polypeptide, even if it were classified as a plasmolipin. These examples and others illustrate that it is not predictable as to which amino acids are necessary to maintain the functional characteristics of a protein, and that even very high homology is not necessarily predictive of function.

The specification teaches the polypeptide of SEQ ID NO: 4. The claims are directed to a polypeptide that bears 67-87% homology to a rat plasmolipin. Applicants argue (pp. 3-5, Paper No. 14, 14 August 2001) that homology of the disclosed polypeptide with a class of proteins *already having* utility shall impart specific and substantial utility on the novel polypeptide. However, the polypeptide of the Instant Application is, as yet, an unidentified molecule. The specification does not teach the skilled artisan how to *use* the disclosed polypeptide for *any* unique or specific purpose. For example, there is no disclosure of transduction processes in transfected cells, or the phenotypes of "knock-in" or "knock-out" organisms, or binding assays,

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or cell-proliferation assays, or of diseases caused by an overactivity or underactivity of the disclosed protein. Therefore, the skilled artisan is not provided with sufficient guidance to use the claimed polynucleotides for any purpose.

Applicants argue against the Utility and Enablement rejection by further discussing the similarity of the polypeptide of SEQ ID NO: 4 to the plasmolipins, a family of transmembrane proteolipids related, for example, to the connexins. Although there is no evidence that the claimed protein functions as a plasmolipin, were it established as such, additional specific functional assays would be needed as discussed above, since homology is insufficient to impart utility on a novel protein.

It should be noted that the paper submitted with the amendment of 14 August 2001 (Gillen, et al 1999, European J Neuroscience, 8: 405-414) is not officially of record, since it was not documented in a PTO form 1449.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

10/24/01

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER